

REMARKS

Claims 5-8 and 10-93 are pending and under examination. Claims 21, 22, 49, 50, 52, 57, 58, 66, 67 and 74-76 stand rejected under 35 U.S.C. § 102(b) over Chinese Patent Application Disclosure No. 1113234 (Wu Gousheng). Claims 5-8, 10-20, 23-48, 51, 53-56, 59-65, 68-71 and 77-92 stand rejected under 35 U.S.C. 103(a) over Wu Gousheng.

In response to the Examiner's comments on page 3 of the Office Action, Applicants respond that all inventors have assigned rights to the present invention to the common assignee Teva Pharmaceuticals under the assignment document filed April 1, 2002.

Applicants thank the Examiner for the courtesy of affording their representative an interview on March 2, 2004. Pursuant to 37 C.F.R. § 1.133, Applicants summarize the substance of that interview. At the interview, Applicants' representative indicated Applicants' desired to focus the Examiner's attention on claims 19-21 and 25-48 directed to anhydrous ondansetron hydrochloride and processes for preparing it. Applicants' representative asserted that Wu Gousheng does not disclose anhydrous ondansetron hydrochloride or a way of making it, pointing to Embodiment A₁ of the reference where vacuum drying of ondansetron hydrochloride dihydrate over P₂O₅ yielded a monohydrate of ondansetron hydrochloride, not anhydrous ondansetron hydrochloride. The Examiner indicated that amendment of claim 21 to recite that Form B is anhydrous and that it is "polymorphic" would be favorably considered.

Claim 5 has been rewritten in independent form. The claim was amended to remove dependency on previously canceled claim 1.

Claims 21, 22, 39, 40, 41, 42, 43, 44, 45 and 46 have been amended as recommended by

the Examiner to recite that Form B is anhydrous and polymorphic.

Claim 22 also has been amended to make it dependent on claim 21.

Claims 23, 25 and 32 have been amended to change their multiple dependency to claims 21 and 22.

Claims 39, 41, 43 and 45 have been amended to make them dependent upon claim 21, thereby incorporating the subject matter of claim 21.

Claims 27, 29, 31, 32, 34, 36 and 38 have been amended to correct grammatical errors.

No new matter has been added.

Claim 47 has been amended to correct a typographic error. Ondansetron base, not ondansetron hydrochloride, is dissolved in toluene. Support for the amendment can be found at page 10, lines 16 and 17 of the application.

Claim 48 has been amended by replacing the term "gaseous hydrochloride" with "HCl gas" because the latter term has antecedent basis in claim 46 while the former does not. Claim 48 has also been amended to make explicit that the toluene solution contains "ondansetron base." No new matter has been added and support for the amendments can be found at page 10, lines 16 and 17 of the application.

Claim 49 has been amended to describe the peaks at 6.3 and 24.4 as "strong." This amendment is supported by the specification at page 11, lines 13-15.

Claims 57 and 58 have been amended to correct typographical errors. These amendments are supported by the specification at page 12, lines 10-12.

If the Examiner determines that claims 21-48 are in condition for allowance, Applicants'

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authorization is hereby given to cancel claims 5-20 and 49-93 without prejudice by Examiner's amendment for the purpose of placing the application in condition for allowance.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that claims 21-48 are in condition for allowance. Early and favorable action by the Examiner is earnestly solicited. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is urged to telephone the undersigned at the number below. The undersigned may also be contacted by email at dziker@kenyon.com.

Respectfully Submitted,

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